IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Deborah E. Wilson et al.
Application No.: 10/597,191
Filed: November 7, 2006
Confirmation No.: 7477
For: METHOD AND APPARATUS FOR BIOWEAPON DECONTAMINATION

FILED BY EFS

Examiner: Jennifer A. Smith
Art Unit: 1793
Attorney Reference No.: 4239-64793-03

FILED BY ELECTRONIC FILING SYSTEM
UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION UNDER 37 C.F.R. § 1.131

1. We, Drs. Deborah E. Wilson and Murray L. Cohen, and Katherine K. Lock, Thomas E. McWhorter, Aaron L. Rosenblatt and Theodore J. Traum are co-inventors named in the above-referenced patent application, and co-inventors of the subject matter described and claimed therein. We have read and understand the current claims.

2. Prior to the September 10, 2002, provisional application filing date of Nelson *et al.* (US Patent Application No. 60/409,827), we had conceived and reduced to practice the invention described and claimed in the subject application in this country, as evidenced by the following.

3. We conceived and reduced the invention to practice in laboratories at the National Institutes of Health, USA, as shown in Exhibit A, attached.

4. Exhibit A is a copy of a PowerPoint Presentation given to the Technical Support Working Group (TSWG), Department of Defense, prior to the provisional application filing date of Nelson *et al.* (September 10, 2002). Any information presented in the PowerPoint presentation that should not be made publicly available has been redacted in this version of the presentation. The PowerPoint presentation discloses a method of decontamination and in

particular, a method of decontaminating mail or other items that are contaminated with a bioterrorism agent such as *Bacillus anthracis* or weaponized anthrax. The method uses unique decontamination cycles, defined by specific concentrations and atmospheric conditions of chlorine dioxide gas to decontaminate an object. As evidenced by Exhibit A, the PowerPoint presentation contains diagrams and photographs of the claimed apparatus. Exhibit A also contains preliminary test data after execution of the claimed decontamination method. The same data and features of the apparatus can be found in the inventor's provisional application filed January 16, 2004 (US Patent Application No. 60/537,457). For example, page 17 of the PowerPoint presentation corresponds with the claimed decontamination apparatus, and is also disclosed as Figure 1 in the instant application. In addition, pages 18-20 of the PowerPoint presentation disclose specific components of the claimed decontamination apparatus as found in Figures 1 and 3 of the instant application. Specifically, page 18 of the PowerPoint presentation shows a photograph of a "CDG Laboratory Mail Process Reactor". A schematic of the CDG Laboratory Mail Process Reactor is shown in Figure 3 of the instant invention (90). Page 19 of the PowerPoint presentation reports a "CDG Laboratory ClO_2 Generator and Process Controller". The ClO_2 Generator and Process Controller correspond to features (32) and (22) of Figure 1 found in the instant application. Furthermore, page 20 of the PowerPoint presentation shows a "CDG Laboratory Humidification Chamber" that corresponds with component (14) of Figure 1 in the instant application.

5. Pages 22-28 of the PowerPoint presentation disclose preliminary test results of the claimed decontamination method using chlorine dioxide gas. The data from pages 22-28 correspond to Examples 1-5 of the inventor's provisional application (US Patent Application No. 60/537,457).

6. Page 22 of the PowerPoint presentation demonstrates a method of decontaminating mail at a concentration of 10,000 ppm chlorine dioxide gas over a period of 4 hours. In this experiment, 16 paper filters were contaminated with 2×10^8 weaponized spores (WBI) and were exposed to 10,000 ppm ClO_2 gas for four hours. The filters were cultured under permissive culture conditions to determine whether the spores were viable following the decontamination protocol. None of the 16 filters showed viable spores following

decontamination thus, a concentration of 10,000 ppm ClO_2 gas is an effective sterilant for paper contaminated with weaponized spores. The data presented on page 22 of the PowerPoint presentation corresponds with Example 1 of the provisional patent application.

7. Pages 23 and 24 of the PowerPoint presentation demonstrate the effect of a pre-humidification step (95% relative humidity; 95°F for 1-3 hours) on the decontamination protocol. In this experiment, paper filters were contaminated with 2×10^8 weaponized spores (WBI)(n=2), 10×10^{10} weaponized spores (n=2), or 2×10^6 conventional biological indicator (BI) spores (n=2) and exposed to 10,000 ppm ClO_2 gas for 4 hours. The filters were cultured under permissive culture conditions to determine whether the spores were viable following the pre-humidification and decontamination protocol. None of the 6 filters showed viable spores following pre-humidification and decontamination. The data presented on pages 23 and 24 of the PowerPoint presentation correspond to Example 2 of the provisional patent application.

8. Pages 25 and 26 of the PowerPoint presentation demonstrate the effect of chlorine gas concentrations on the decontamination protocol. In this experiment, paper filters were contaminated with 2×10^8 weaponized spores (n=2), 10×10^{10} weaponized spores (n=2), or 2×10^6 conventional biological indicator spores (n=2) were enclosed in envelopes and pre-humidified at 95% relative humidity and 95°F for 1.5 hours. The samples were then exposed to 2,500, 1,000 or 500 ppm ClO_2 gas for 4 hours. The filters were cultured under permissive culture conditions to determine whether the spores were viable following the pre-humidification and ClO_2 gas decontamination protocol. Only the filters containing weaponized spores that were exposed to the lowest concentration of ClO_2 gas (500 ppm) showed viable spores following pre-humidification and decontamination. The data presented on pages 25 and 26 of the PowerPoint presentation correspond to Example 3 of the provisional patent application.

9. Page 27 of the PowerPoint presentation demonstrates the inadequacy of using conventional biological indicators (BI) to measure the decontamination efficacy of chlorine dioxide bioweapon decontamination protocols. In this experiment, paper filters were contaminated with 2×10^6 weaponized spores or 2×10^6 conventional biological indicator spores, enclosed in envelopes and pre-humidified at 95% relative humidity and 95°F for 1.5

hours. The samples were then exposed to 500 ppm ClO_2 gas for 4 hours. The filters were cultured under permissive culture conditions to determine whether the spores were viable following the decontamination protocol. Following decontamination, the weaponized spores were still viable, whereas the conventional biological indicator spores were not. The data presented on page 27 of the PowerPoint presentation corresponds with Example 4 of the provisional patent application.

10. Page 28 of the PowerPoint presentation demonstrates the inadequacy of steam sterilization for decontaminating weaponized spores. In this experiment, paper filters were contaminated with 10^{10} weaponized spores or 10^{6} conventional biological indicator spores, enclosed in envelopes and exposed to a steam decontamination protocol for 15 minutes at 121°C and a pressure of 20 pounds per square inch (PSI). The filters were cultured under permissive culture conditions to determine whether the spores were viable following the decontamination protocol. Following decontamination, the weaponized spores were still viable, whereas the conventional biological indicator spores showed no growth. The data presented on page 28 of the PowerPoint presentation corresponds with Example 5 of the provisional patent application.

11. The Nelson *et al.* (US Published Patent No. 2004/0101438) application was published on May 27, 2004, and claims the benefit of priority to Provisional Patent Application No. 60/409,827 filed September 10, 2002. As demonstrated by Exhibit A, we were in possession of the claimed invention prior to September 2002. We hereby declare that the PowerPoint presentation and data provided therein was made prior to the filing date of the provisional application by Nelson *et al.* (US Patent Application No. 60/409,827 filed September 10, 2002), and that the claimed invention was not publicly disclosed until the inventors filed a provisional patent application on January 16, 2004 (US Patent Application No. 60/537,457).

12. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such

willful false statements may jeopardize the validity of the application or any patent issued thereon.

Deborah E. Wilson	Date
Murray L. Cohen	Date
Katherine K. Lock	April 23, 2009 Date
Thomas E. McWhorter	Date
Aaron L. Rosenblatt	Date
Theodore J. Traum	Date

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6. Page 22 of the PowerPoint presentation demonstrates a method of decontaminating mail at a concentration of 10,000 ppm chlorine dioxide gas over a period of 4 hours. In this experiment, 16 paper filters were contaminated with 2×10^8 weaponized spores (WBI) and were exposed to 10,000 ppm ClO_2 gas for four hours. The filters were cultured under permissive culture conditions to determine whether the spores were viable following the decontamination protocol. None of the 16 filters showed viable spores following

decontamination thus, a concentration of 10,000 ppm ClO_2 gas is an effective sterilant for paper contaminated with weaponized spores. The data presented on page 22 of the PowerPoint presentation corresponds with Example 1 of the provisional patent application.

7. Pages 23 and 24 of the PowerPoint presentation demonstrate the effect of a pre-humidification step (95% relative humidity; 95°F for 1-3 hours) on the decontamination protocol. In this experiment, paper filters were contaminated with 2×10^8 weaponized spores (WBI)(n=2), 10×10^{10} weaponized spores (n=2), or 2×10^6 conventional biological indicator (BI) spores (n=2) and exposed to 10,000 ppm ClO_2 gas for 4 hours. The filters were cultured under permissive culture conditions to determine whether the spores were viable following the pre-humidification and decontamination protocol. None of the 6 filters showed viable spores following pre-humidification and decontamination. The data presented on pages 23 and 24 of the PowerPoint presentation correspond to Example 2 of the provisional patent application.

8. Pages 25 and 26 of the PowerPoint presentation demonstrate the effect of chlorine gas concentrations on the decontamination protocol. In this experiment, paper filters were contaminated with 2×10^8 weaponized spores (n=2), 10×10^{10} weaponized spores (n=2), or 2×10^6 conventional biological indicator spores (n=2) were enclosed in envelopes and pre-humidified at 95% relative humidity and 95°F for 1.5 hours. The samples were then exposed to 2,500, 1,000 or 500 ppm ClO_2 gas for 4 hours. The filters were cultured under permissive culture conditions to determine whether the spores were viable following the pre-humidification and ClO_2 gas decontamination protocol. Only the filters containing weaponized spores that were exposed to the lowest concentration of ClO_2 gas (500 ppm) showed viable spores following pre-humidification and decontamination. The data presented on pages 25 and 26 of the PowerPoint presentation correspond to Example 3 of the provisional patent application.

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Deborah E. Wilson	Date
Murray L. Cohen	Date
Katherine K. Lock	Date
Thomas E. McWhorter	2/20/09 Date
Aaron L. Rosenblatt	Date
Theodore J. Traum	Date

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